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REPORT TO CONGRESS

COBRA MEDICARE PREVENTION DEMONSTRATION

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COBRA MEDICARE PREVENTION DEMONSTRATION EVALUATION

EXECUTIVE SUMMARY

INTRODUCTION

In 1985, as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA), Congress mandated a national demonstration to test the effectiveness of providing disease prevention and health promotion services to Medicare beneficiaries. Certain stipulations were included:

- no fewer than five sites, one of which is rural;
- administration of each program by an accredited public health school or preventive medicine department;
- a maximum Federal expenditure of $5.9 million for the demonstration and its evaluation;
- inclusion of at least one cancer screening component;
- provision of a package of preventive services, under waivers, to include health screenings, health risk appraisals, immunizations and counseling/instruction in several areas (diet, stress reduction, smoking cessation, etc.); and
- tests of the relative effectiveness of alternative practitioners and practitioner combinations, in providing preventive services.

The Health Care Financing Administration (HCFA) included as an additional recommendation in its solicitation for applications, the use of standard demonstration design techniques, including random assignment of beneficiaries to experimental and control groups.

Over a 4-year period, projects are to plan (6 months), provide services (2 years), and evaluate their own programs (18 months). Within a cost-effectiveness framework, projects are to evaluate the effect of offering preventive services on Federal health care expenditures; utilization of institutional and noninstitutional services; health status and functional independence; incidence of screened conditions, adjusting for false negative and false positive results; health behavior and awareness; and utilization of nonphysician providers.

Abt Associates Inc., was selected to complete a cross-cutting evaluation of the demonstration.

Review Process

In August 1987, 3 months after HCFA's solicitation for preventive services appeared in the Federal Register, 11 schools of public health had submitted proposals to participate in the demonstration. HCFA convened an independent review panel to select demonstration projects.

In April 1988. HCFA awarded cooperative agreements to five institutions:

- The Johns Hopkins University, School of Hygiene and Public Health.
- San Diego State University, School of Public Health.
- University of California at Los Angeles (UCLA), School of Public Health.
- University of Pittsburgh, School of Public Health.
- University of Washington, School of Public Health and Community Medicine.

After a planning period, the projects began delivering services in the spring of 1989.

RESEARCH DESIGNS OF THE DEMONSTRATION PROJECT

In general, the preventive service package, the demonstration intervention, is composed of four components: health screenings, health risk appraisals, immunizations, and counseling and education on a variety of topics (e.g., medication use, nutrition). The intervention generally includes a routine history, laboratory tests, blood pressure/hypertension screening, and a basic exam of the patients' height, weight, vision, and hearing. However, each project had the option to include additional services to the prevention package, such as dental screening and referral or breast cancer screening. None will explicitly offer mammography as part of the demonstration because mammography will be reimbursed under the Medicare Catastrophic Coverage Act of 1988. HCFA is currently negotiating annual all-inclusive rates for the preventive services package with each project; in some cases, separate rates will be negotiated for specific components of the intervention.

To test the feasibility and cost-effectiveness of providing preventive health services to Medicare beneficiaries, each project is randomly assigning beneficiaries to a treatment (or experimental) group and a control group. Both groups receive a health risk appraisal (HRA) to identify baseline health status and behavior characteristics. The HRA is also conducted at the end of year 1 for both groups to compare trends in health status and behavior. However, only the experimental group will receive the intervention, or the preventive service package.

Most of the projects awarded cooperative agreements for this demonstration are located in large metropolitan areas. However, the University of Pittsburgh plans to serve several rural counties in western Pennsylvania. Of the five projects, Johns Hopkins will be serving the most disadvantaged Medicare populations measured by the percentage of the population that is nonwhite, and income level.

Brief descriptions of each demonstration project are presented below, including characteristics of the sampling frame and additional services provided as part of the prevention package.

UCLA: Approximately 1,600 Medicare beneficiaries who are patients of the university-based clinic will be targeted for the preventive service demonstration. In addition to the basic preventive service package, UCLA will be providing dental referral services.

Washington: Approximately 3,000 Medicare beneficiaries who have not been involved in previous health promotion studies enrolled in one of three Group Health Cooperative Health Maintenance Organization (HMO) clinics will be targeted for the preventive service demonstration. Treatment groups will be stratified by high and low utilizers. In addition to the basic preventive service package, Washington will be providing several cancer screenings and examinations (including breast) and counseling on planning for the future and on appropriate utilization of services.

Johns Hopkins University: Approximately 6,000 Medicare beneficiaries in Baltimore City will be targeted for the preventive services demonstration. Treatment groups will be stratified by four types of providers: 1) hospital-based providers; 2) community-based group practice; 3) community-based physician in solo or group practices; and 4) no regular physician. In addition to the basic preventive service package, Johns Hopkins will provide dental/periodontal screening, and several cancer screenings and examinations (including breast).

Pittsburgh: Approximately 10,000 Medicare beneficiaries residing in rural counties in western Pennsylvania will be targeted for the preventive services demonstration.

San Diego: Approximately 2,400 Medicare beneficiaries enrolled in the Secure Horizons HMO will be targeted for the preventive services demonstration. Treatment groups will be stratified by three age cohorts.

Evaluation

Each project is responsible for evaluating its own demonstration. All five projects plan to test hypotheses regarding the effect of preventive services on cost, utilization of health care services, and functional/health status.

The cross-cutting evaluation will use data from all five demonstration projects to attempt a general assessment of the feasibility of providing preventive services to Medicare beneficiaries.

Two major issues will be addressed:

- What were the differences and similarities in experiences of the five separate demonstration projects in enrolling beneficiaries and providers, providing preventive and follow-up services, tracking utilization, and attaining stated goals and objectives?

- Is it cost-effective to provide disease prevention and health promotion services for the elderly population, given the outcomes in the demonstration project?

The short time period for this study (6 month start up, 2 years of demonstration and 18 months for evaluation) will make it difficult to observe many of the outcomes that should follow from a prevention intervention; this is the reason for emphasizing feasibility in this evaluation.

Hypotheses that will be tested in the cross-cutting evaluation cover short and long-run effects of prevention services on Medicare expenditures, hospital admissions and lengths of stay, nursing home days, physician and home health care visits, beneficiary health status, and beneficiary health related behavior.

At the conclusion of this study, the final Report to Congress will include the analysis of the feasibility and impact of the preventive service demonstration, as well as discussion of options for the Medicare program in designing a prevention benefit, including observations on potential financing methods.

1.0 INTRODUCTION

In 1985, Congress mandated a national demonstration to test the effectiveness of providing disease prevention and health promotion services to Medicare beneficiaries. This report describes the five demonstration programs that will be implemented and summarizes the methods the Health Care Financing Administration (HCFA) will use to evaluate them.

1.1 Legislative Background

Under the mandate of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), HCFA initiated a 4-year demonstration program designed to reduce disability and dependency among the elderly through the provision of preventive health services to individuals entitled to benefits under title XVIII of the Social Security Act. Under this demonstration, HCFA will provide reimbursement for preventive services that are not usually covered by Medicare. An evaluation of this demonstration will determine the impacts of the demonstration on overall health care utilization and costs, particularly changes in utilization of inpatient and other provider services (e.g., skilled nursing facilities (SNFs)) for conditions that the package is targeted to prevent.

Projects must be conducted under the direction of accredited public or private nonprofit schools of public health, or preventive medicine departments accredited by the Council on Education for Public Health. The legislation specifies that the demonstration must be conducted in no fewer than five

sites, with at least one project in a rural area. Funding for administrative costs (e.g., research and evaluation costs of each project) will be included in the $5.9 million that is authorized for this demonstration.[1]

Medicare reimbursement is limited to covered services that are reasonable and necessary for the treatment of an illness or injury. With the exception of a specific statutory authorization to cover immunizations for pneumococcal pneumonia, hepatitis B and mammography, Medicare does not cover primary preventive services. Under this demonstration, however, the following preventive services will be available through waivers:

- Health screenings (e.g., hearing, vision, blood pressure, height and weight);
- Health risk appraisals (HRA);
- Immunizations; and
- Counseling on and instruction in:
  - diet and nutrition,
  - stress reduction,
  - exercise and exercise programs,
  - sleep regulation,
  - injury prevention,

[1] Section 9314 of Public Law 99-272; Section 9344(d)(1) and (d)(2) of Public Law 99-509.

- alcohol/drug abuse,

- mental health disorders,

- smoking reduction or cessation, and

- self care and medication use.

Congressional intent was that at least one of the five projects include a cancer screening component, including breast cancer screening. Reimbursement for treating conditions identified under this demonstration was not intended to be a part of this project.

The legislation identified two design issues. The first issue is testing alternative payment methods for preventive services, including prepayment as well as payment on a fee-for-service basis. HCFA elaborated on this design feature in the solicitation to potential awardees.[1] Prepayment under this demonstration is considered to be payment to providers of preventive services as a package prior to the delivery of services, while fee-for-service is the payment of preventive services as each service or group of services is delivered by providers. A single rate per service or group of services that would be provided during a single visit was recommended in the solicitation for the payment rate for fee-for-service project designs. For prepayment projects, a payment rate for the complete package of services is required as well as a detailed payment rate methodology on how the rate was developed. HCFA reserved the right to establish a uniform annual maximum rate that it will pay for the package of services provided for both payment models.

HCFA also specified in the solicitation that it was interested in testing the feasibility of cost sharing options for projects with fee-for-service designs. (The cost sharing is accounted for in the calculation of the premium for Medicare beneficiaries for projects with prepayment

[1] Special Solicitation for Preventive Services, Federal Register Vol. 52, No. 103, May 29, 1987.

approaches.) HCFA was particularly interested in funding a project that was designed with half of the beneficiaries responsible for cost sharing (both deductible and coinsurance) and the other half with the cost sharing responsibility for preventive services waived.

The second design issue specifically identified in the legislation addressed testing the effect of permitting a variety of health care practitioners to furnish the preventive health services. Projects are to be designed to allow any combination of physicians, health educators, nurses, allied health personnel (physician assistant or nurse practitioner), dieticians, and clinical psychologists to deliver the preventive services.

A primary objective of these demonstrations is to measure the cost effectiveness of providing preventive services to Medicare beneficiaries. As a result, the solicitation emphasized the importance of randomly assigning Medicare beneficiaries to experimental and control groups to assure valid measurement of the prevention efforts. Stratification of the sample according to levels of risk for specific diseases or other factors that might impact the overall design of the demonstration and evaluation was also recommended, if appropriate.

These projects were allowed up to 6 months for development and design prior to becoming operational. The preventive services will be provided during a 2-year demonstration period, beginning in the spring of 1989, followed by an 18-month period for analysis and submission of an evaluation report.

Each site is responsible for an evaluation of its demonstration effort. Since sites will have varied approaches to delivering preventive services to Medicare beneficiaries, the evaluations will address different issues. However, to the extent possible, each site must base its research and evaluation design on the following issues:

- The short and long-term costs and savings to the Government attributable to the expanded coverage of preventive services;

- Changes in utilization of inpatient and other provider-related services for conditions that the preventive package is targeted to prevent;

- Changes in utilization of preventive services caused by the experimental coverage;

- Changes in the health status and functional independence among the experimental group;

- Changes in the incidence of conditions and associated costs for which screening procedures are given among the experimental group;

- Changes in health behavior, lifestyle practices, and awareness and understanding among the experimental and control groups;

- The impact of utilizing nonphysician providers for the preventive services; and

- The impact of false negative and false positive results in the clinical screening procedures.

In addition to each sites' evaluation report, HCFA has contracted with Abt Associates Inc., (AAI) to synthesize the results and complete a cross-cutting evaluation.

1.2 Selection of Projects

The special solicitation for preventive services appeared in the Federal Register on May 29, 1987. Proposals from interested awardees were due to HCFA by August 27, 1987, 3 months after the solicitation appeared in the Federal Register. Eleven institutions submitted proposals and the usual HCFA review process was used to evaluate the proposals for this special solicitation. This process included several tasks, including convening an independent review committee; preparing summaries and critiques of each submitted proposal; submitting questions for clarification, if necessary, to any potential awardee; and specifying conditions of award.

Several criteria were used to evaluate each application. Of primary importance was the proposed design of the demonstration and evaluation, including the adequacy and creativity of the demonstration and evaluation design and hypotheses, validity and appropriateness of relevant statistical techniques, methods, and data base(s) proposed, and the methodological preciseness and consistency with current state-of-the-art techniques.

The review panel submitted its final recommendations to HCFA based on these criteria and the discussions held at the panel meeting. HCFA awarded cooperative agreements to the following five institutions:

- University of Washington
- Johns Hopkins University
- University of Pittsburgh
- University of California at Los Angeles (UCLA)
- San Diego State University

The awardees were notified on April 29, 1988. HCFA placed several conditions upon award that each institution was required to meet.

Demonstration sites will be operational and delivering services by spring of 1989. As a result, sites undertook the following activities during the first year developmental period:

- the demonstration protocol were written in detail and approved by HCFA;
- provider agreements and reimbursement arrangements were secured;
- sampling frames and methodology were identified;
- enrollment strategies and marketing efforts were designed;

- data systems were developed and tested; and
- waiver cost estimates were developed and waivers approved.

The demonstration sites have completed these activities. The next chapter discusses and compares the design of each demonstration.

2.0 RESEARCH DESIGNS OF THE DEMONSTRATIONS PROJECTS

2.1 Overview

The sociodemographic characteristics of the populations served by each demonstration project are quite similar. About 10 percent of the general population are over 65 years old and the majority are white women. The preventive services package will be delivered through community-based and affiliated providers or through Health Maintenance Organization (HMO) settings. Each mode of delivery presents unique marketing, sampling, and service delivery challenges.

In general, the preventive service package, the "demonstration intervention," is similar across all five demonstration projects. Each project's intervention is composed of four components: health screenings, health risk appraisals (HRA), immunizations, and counseling and education on a variety of topics (e.g., medication use, and nutrition). The intervention generally includes a general routine history, laboratory tests, blood pressure/hypertension screening, and a basic exam of the patient for height, weight, vision, and hearing. However, each project had the option to include additional services in the prevention package, such as dental screening and referral or breast cancer screening. Most demonstration providers will receive an annual all-inclusive rate for the preventive services package.

To test the feasibility and cost-effectiveness of providing preventive health services to Medicare beneficiaries, each project is randomly assigning beneficiaries to a treatment (or experimental) group and a control group. Both groups receive an HRA to identify baseline health status and behavior characteristics. The HRA is also conducted at the end of year 1 for both groups to compare trends in health status and behavior. However, only the experimental group will receive the intervention, or the preventive service package.

The hypotheses and data collection strategies of each demonstration will be incorporated into each project's individual evaluation of the demonstration project. For that reason, the hypotheses tend to differ across projects according to each project's demonstration design. Each project is

employing different data collection instruments to measure changes in functional and health status. In general, however, each project will be measuring the level of functional ability with respect to mobility and limitations of activities. Perceived quality of life and general well-being measures are also being collected.

Brief descriptions of each demonstration project are presented below, including characteristics of the sampling frame, additional services provided as part of the prevention package, and the reimbursement rates.

UCLA: Approximately 1,600 Medicare beneficiaries who are patients of the university-based clinic will be targeted for the preventive service demonstration. In addition to the basic preventive service package, UCLA will be providing dental referral services. UCLA will be reimbursed a flat annual rate of $150 per participant for the initial screening and health promotion services.

University of Washington: Approximately 3,000 Medicare beneficiaries who have not been involved in previous health promotion studies enrolled in one of the three Group Health Cooperative (GHC) HMO clinics will be targeted for the preventive service demonstration. Treatment groups will be stratified by high and low utilizers. In addition to the basic preventive service package, Washington will be providing several cancer screenings and examinations (including breast) and counseling on planning for the future and on appropriate utilization of services. The University of Washington will be reimbursed a flat rate of $154.75 for the initial screening and health promotion services.

Johns Hopkins University: Approximately 6,000 Medicare beneficiaries in Baltimore city will be targeted for the preventive services demonstration. Treatment groups will be stratified by the participants' usual source of primary care: 1) hospital-based providers; 2) community-based group practice; 3) community-based

physician in solo or group practices; and 4) no regular physician. In addition to the basic preventive service package, Johns Hopkins will provide dental/periodontal screening, and several cancer screenings and examinations (including breast). Johns Hopkins University will be reimbursed $120 for a combined physician and counseling visit; $25 for laboratory tests; and $40 for each counseling session required during the year.

University of Pittsburgh: Approximately 10,000 Medicare beneficiaries residing in rural counties in western Pennsylvania will be targeted for the preventive services demonstration. The University of Pittsburgh will be reimbursed $30 for each in-home HRA, and $150 for the initial screening and health promotion services.

San Diego State University: Approximately 2,400 Medicare beneficiaries enrolled in the Secure Horizons HMO will be targeted for the preventive services demonstration. Treatment groups will be stratified by three age cohorts. San Diego State University will be reimbursed a flat rate of $122.48 for the initial screening and health promotion services.

The following sections review the background of the population served by each project, the general design features of each demonstration, and the hypotheses and data collection strategies that will be employed. Many of the design elements were being developed at the time this report was prepared. As a result, this chapter reflects the status of each project's developmental activities as of the fall of 1988.

2.2 Demographic Characteristics of Projects

The population of the demonstration projects do not vary substantially in terms of sociodemographic characteristics of the individuals targeted to receive the preventive services (see Exhibit 2-1). Most of the demonstration sites are in large, metropolitan areas of one million or more population. Only the University of Pittsburgh demonstration will serve a rural population. Although specific rural counties in Pennsylvania have not been selected, this report illustrates the area's characteristics with figures that represent Jefferson County.

The educational and income levels of the general population tend to vary among the projects. About 70 percent or more of the general population are high school graduates, except in the areas served by Johns Hopkins University and in a rural county in western Pennsylvania. Per capita incomes range from about $9,000 in the rural county of western Pennsylvania to slightly over $13,500 in the area served by the University of Washington demonstration project.

About 10 percent of the total population are over 65 years in three of the areas served by demonstration projects (UCLA, University of Washington, and San Diego State University). The aged population in the other two demonstration projects represents a higher proportion of the general population. Almost 13 percent and 15 percent of the total population are over 65 years old in the areas served by Johns Hopkins University and the University of Pittsburgh, respectively.

With some notable exceptions, target populations are similar in gender and ethnicity. About 60 percent are women, and most of the elderly are white. There is practically no minority population in the rural areas served by the University of Pittsburgh. However, about one-third of the elderly in the area served by Johns Hopkins University is nonwhite.

Information relating to the health status of the target population was provided in the applications submitted by several of the selected demonstration projects. For example, the majority (over 80 percent) of the elderly (65-84 years old) in the population served by the Johns Hopkins University demonstration project do not experience difficulties with their activities of daily living (ADLs). Not surprisingly, however, 40 percent of the

Exhibit 2-1

Socio-Demographic Characteristics of Target Population

	UCLA[a]	Washington[b]	Johns Hopkins[c]	Pittsburgh[d]	San Diego[e]
Area Served	Los Angeles County	King County	Baltimore City	Rural Western Pennsylvania	San Diego County
Total Population	7,477,503	1,269,749	786,775	48,303	1,861,846
Education					
High School Graduate	69.8%	82.6%	48.4%	62.4%	78.0%
Per Capita Income	$12,544	$13,675	$9,842	$8616	$10,951
Total Population	743,005	129,414	100,575	7037	191,744
Age 65+	(9.9%)	(10.2%)	(12.8%)	(14.6%)	(10.3%)
Sex					
Male	38.8%	39.5%	37.9%	41.6%	41.2%
Female	61.2%	60.5%	62.1%	58.4%	58.8%
Race					
White	83.9%	93.5%	65.9%	99.8%	93.9%
Minority	16.1%	6.5%	34.1%	0.2%	6.2%

a. Based on Los Angeles County, CA
b. Based on King County, WA
c. Based on Baltimore City, MD
d. Based on Jefferson County, PA
e. Based on San Diego County, CA

Source: 1980 Census

old elderly (85 years old and above) reported ADL impairment.

Similarly, the majority of the elderly in the areas served by the San Diego State University and the University of Washington demonstration projects rate their health as good or excellent, despite the prevalence of several chronic conditions. For example, about half of the elders in the areas served by the University of Washington and Johns Hopkins University projects report having a chronic condition of arthritis. About 10-15 percent of the elderly in these two areas also have chronic heart conditions.

2.3 General Design Features

As shown in Exhibit 2-2, the general design of the demonstrations vary by project. As mentioned above, the University of Pittsburgh demonstration project will serve Medicare beneficiaries in a rural area of western Pennsylvania. The other four projects typically will serve Medicare beneficiaries residing in large, urban areas.

The sampling frame from which the projects will select Medicare beneficiaries can be based either on the provider or the area served. For the three provider-based demonstration projects, UCLA, University of Washington, and San Diego State University, beneficiaries will be selected from the patients of the physicians or clinics associated with the demonstration project. In the latter two cases, the sample will be selected from the HMOs (GHC of Puget Sound and the Secure Horizons HMO) that will provide services. Outreach efforts are generally less burdensome for provider-based designs since there is an identifiable and discrete population. However, the potential for a biased sample is higher for these types of designs.

In population-based designs, as in the Johns Hopkins University and University of Pittsburgh projects, Medicare beneficiaries will be selected from the geographic area served by the demonstration project. This typically involves a sampling plan based on certain zip codes in the area. While marketing and enrollment efforts must be more sophisticated for beneficiaries in an entire geographic area (rather than for an identified group of patients), the sample is more likely to be representative of the Medicare population as a whole.

Exhibit 2-2

Design Features of Demonstrations

	UCLA	WASHINGTON	JOHNS HOPKINS	PITTSBURGH	SAN DIEGO
ocation	Urban	Urban	Urban	Rural	Urban
ampling Frame	Provider-Based	Provider-Based	Population-Based	Population-Based	Provider-Based
elivery System	University-based clinic	HMO (GHC of Puget Sound)	Hospital OPD/Clinic and Community-based Providers	Special Prevention Centers and Physicians	HMO (Secure Horizons)
ates (annual)	$150 for initial screening and health promotion services	$154.75 for initial screening and health promotion services	$120 for a combined physician and counseling visit $25 for lab tests $40 for interval counseling sessions, if required	$30 for in-home Health Risk Appraisal $150 for initial screening and health promotion services	$122.48 for initial screening and health promotion services

The preventive service package will be delivered in a variety of settings. The three demonstration projects that are provider-based will rely on delivering services through their affiliated providers. As mentioned above, two projects will use HMOs as the primary delivery model. The University of Washington will deliver services through the GHC of Puget Sound HMO and San Diego State University will provide the preventive service package through the Secure Horizons HMO. UCLA will deliver the service package through the clinic that is associated with the university.

The two population-based demonstration projects will make arrangements with community-based providers for service delivery. Johns Hopkins University will utilize hospital outpatient departments (OPD), general medicine and specialty clinics, and other community-based providers to deliver the preventive services package. The University of Pittsburgh will designate special Prevention Centers and physicians in the rural area to provide the preventive services.

Reimbursement for providing the preventive service package will generally be based on an all-inclusive rate for services provided as part of the demonstration projects. HCFA is currently negotiating these payment rates with each project. In general, most projects will be reimbursed a flat annual rate for the initial screening and health promotion services. For example, three projects (UCLA, Washington, and San Diego) will be paid in this manner. San Diego, UCLA, and Washington will be reimbursed at a rate of $122.48, $125.00, and $154.75 respectively. In two projects, HCFA is negotiating separate rates for individual components of the service package. For example, the School of Hygiene and Public Health at Johns Hopkins University will be reimbursed $120 for a combined physician and counseling visit; $25 for laboratory tests; and $40 for each counseling session required during the year. Similarly, University of Pittsburgh will be paid at a rate of $30 for each in-home HRA, and an additional $150 for the initial screening and health promotion services.

2.4 Individual Designs

The specific features of each demonstration are described below in terms of each projects' sample selection, preventive service package, the research hypotheses that will be tested, and the data collection strategies that will be employed.

2.4.1 Sample Design

The population targeted to participate in the preventive services demonstration is based on the sampling frame described above. As shown in Exhibit 2-3, the demonstration projects employing a provider-based design only target Medicare beneficiaries associated with the provider -- the university-based clinics for UCLA and the HMOs for the University of Washington and San Diego State University. However, UCLA will oversample ethnic minorities and beneficiaries over 75 years old. The University of Washington will only enroll beneficiaries previously not involved with health promotion studies and those with the 'high option' plan where a slightly higher premium and preventive services are included.

The two population-based projects will target Medicare beneficiaries residing in the areas served by the demonstration. Johns Hopkins University, for example, will market to beneficiaries residing in seven zip code areas in Baltimore city while the University of Pittsburgh will target residents living in a rural area of western Pennsylvania.

The sample sizes vary considerably by project, in part, due to the size of the target population. The two population-based demonstration projects have the most ambitious sampling plans. The University of Pittsburgh plans to enroll about 10,000 Medicare beneficiaries, 6,600 (75%) of whom will receive the preventive services packages (experimental group). Johns Hopkins University has a planned initial enrollment of 6,000 beneficiaries, half of whom will participate in the experimental group.

Due to the limited number of beneficiaries affiliated with participating providers, provider-based demonstration projects are planning to enroll fewer Medicare beneficiaries than the population-based projects. The projects where preventive services will be delivered through an HMO setting will have an initial enrollment of 3,000 (University of Washington) and 2,400 (San Diego State University) beneficiaries, half of which will receive the prevention services. UCLA plans to enroll 1,600 Medicare beneficiaries who are patients of the UCLA clinic. Slightly over half (900) will be in the experimental group.

Exhibit 2-3

Sample Design of Demonstrations

	UCLA	WASHINGTON	JOHNS HOPKINS	PITTSBURGH	SAN DIEGO
Target Population	Medicare beneficiaries who are patients of about 150 university-based clinical and academic faculty at UCLA Department of Medicine. Ethnic minorities and 75+ year old will be over-sampled.	Medicare beneficiaries (65+ years) not involved in previous health promotion studies enrolled in 1 of 3 GHC clinics. Only high option enrollees will be included (premium for high option is higher than low option and preventive services are covered). The number of participating clinics may be increased to achieve the desired sample size.	Medicare beneficiaries residing in 7 zip code areas in Baltimore City stratified by four provider types: 1) hospital OPD/hospital-based providers; 2) community-based group practice; 3) community-based physician in solo or partnership practice; and 4) no regular provider.	Medicare beneficiaries residing in rural counties in western Pennsylvania. Three cohorts will be studied: 65-67 year olds; 70-72 years olds; and 75-77 year olds.	Medicare beneficiaries enrolled in Secure Horizons HMO.
Sample Size Control (after expected attrition)	700[a] (455)	1500 (1084)	3000 (2320)	3500 (1650)	1200 (600)
Experimental (after expected attrition)	900[a] (585)	1500 (1084)	3000 (2320)	7500 (4950)	1200 (600)
Strata/Subgroups	None	Controls and experimentals will be stratified by high/low utilizers (e.g., 477 low utilizers and 607 high utilizers after 15% annual attrition) in each treatment group.	Controls and experimentals will be evenly stratified among the four provider types (e.g., 580 in each cell).	None	Experimentals and Controls will be stratified by three age cohorts: 65-74; 74-84; 85+

Each project recognizes that there will be a certain amount of attrition due to a variety of reasons (e.g., inconvenience, lack of interest, mortality, etc.). As a result, the actual number of Medicare beneficiaries that participate throughout the 2-year demonstration will be lower than the original enrollment figures. Projects generally assumed about a 30-35 percent attrition rate over the 2-year period; San Diego State University, however, assumed a 50 percent attrition rate.

Several demonstration projects will be stratifying their samples by subgroups or certain characteristics that may have an effect on health care utilization and health status. Beneficiaries participating in the Johns Hopkins University demonstration will be stratified by their regular source of care: 1) hospital OPD/hospital-based providers; 2) community-based group practices; 3) community-based physicians in solo or partnership practices; and 4) residents with no regular provider. Participants in the University of Washington demonstration will be stratified by their use of health services: each treatment group will be stratified by high and low utilization categories. Finally, San Diego will stratify each treatment group by age.

2.4.2 The Intervention Package

The actual service package includes four primary components: health screenings; health risk appraisals; immunizations; and counseling and education. It is important to understand that the preventive service package is not a complete physical, which includes EEGs, EKGs, stress tests, x-rays, etc. Instead, the intervention includes a general routine history, lab tests, blood pressure/hypertension screening, and a basic exam of the patients' height, weight, vision, and hearing. Two projects (UCLA and Johns Hopkins) have included a dental screening as well (see Exhibit 2-4).

All projects (except UCLA) will be providing immunizations as part of the intervention, including influenza and pneumococcal vaccinations. Some projects will also offer immunization against diptheria and/or tetanus.

Exhibit 2.4

Demonstration interventions

	UCLA	Washington	Johns Hopkins	Pittsburgh	San Diego
Routine Blood work (pressure, hypertension)	X	X	X	X	X
Height and weight	X	X	X	X	X
Vision and hearing	X	X	X	X	X
Dental referral	X	-	X	-	-
Immunizations	-	X	X	X	X
Diet and nutrition	X	X	X	X	X
Stress management	X	X	X	-	X
Mental Health and sleep regulation	X	X	X	X	X
Exercise	X	X	X	X	X
Medication awareness	X	X	X	-	X
Alcohol/drug abuse	X	X	X	X	X
Smoking cessation		X	X	X	X
Injury prevention	X	X	X	X	X
Breast exam	-	X	X	-	-
Other exams	-	X	X	-	-
Other exams	-	stool for occult blood; incontinence hematocrit; cancer screening for cervical, colon, prostate, lung, skin	pap smear; pelvic exam; rectal exam; stool for occult blood; urinary incontinence	urinanalysis/ hematocrit; creatinine; glucose tolerance, cholesterol	hematocrit; Sheilen chart
Counseling for high utilizers	-	X	-	-	-
Planning for Future	-	X	-	-	-

As mandated by the legislation, projects will be offering educational and counseling on a variety of health and safety topics. The interventions in all five projects include counseling and education on diet and nutrition; mental health and sleep regulation; exercise; alcohol and/or drug abuse; and injury prevention. Some projects have included additional subject areas for counseling and education. Four of the five projects include instruction on other self-care issues, stress management, smoking cessation, and medication side effects and potential interactions. The University of Washington demonstration has also incorporated an educational component to assist elders in planning for their future and a counseling component for high utilizers of health services.

Several projects also are including cancer screenings. As specified in the Conference Report, the original intention was to fund one project that included a cancer screening component, including breast cancer screening, realizing that the inclusion of mammography may increase the cost of the cancer screening component. However, the recent Medicare Catastrophic Coverage Act of 1988 provides for reimbursement of mammography. As a result, HCFA made the demonstration awards conditional on the exclusion of mammography as an intervention, but allowed projects to include simple breast exams (physical and self-instruction) and other cancer-related exams.

Two projects, University of Washington and Johns Hopkins University, are providing breast exams. In addition to the breast exam, three projects are providing exams to detect other types of cancer, particularly pelvic, cervical, and colon. One project is also providing lung, skin, and prostate cancer screening.

2.4.3 Demonstration Hypotheses

The solicitation required each project to outline the hypotheses that will be tested by the demonstration design. As shown in Exhibit 2-5, the hypotheses fall under three primary categories: the expected effect on cost, utilization, and functional and health status. A few projects expect to test other types of impacts as well.

Exhibit 2-5

Demonstration Hypotheses

	UCLA	WASHINGTON	JOHNS HOPKINS	PITTSBURGH	SAN DIEGO (All hypotheses presented in null form)
Cost	Long term: No difference in net cost of Parts A and B services	Long term: lower costs	Short term: higher ambulatory costs, no inpatient effect Long term: no ambulatory effect, lower inpatient costs	Short term: Medicare cost increase Long term: Part B costs down, or hospital costs down, or slight Medicare savings	No effect on cost
Utilization	Increased use of preventive services	Short term: more preventive services, fewer non-preventive ambulatory services Long term: fewer ambulatory services	Short term: more ambulatory utilization, no inpatient effect Long term: no ambulatory effect, lower inpatient utilization	Lower hospital utilization	No effect on utilization No difference in out-of-plan utilization
Functional/ Health Status	Higher level of functional status Reduced health risk factors	Long term: 50% slower functional decline	Same health status Improved health-related behavior Lower mortality, institutionalization, disability, better health status, in long term	Lower mortality, morbidity Limited ADL effects	No difference in: health status, mortality, physical limitations, health related behaviors
Other	Outcomes for isolated elderly worse than for elderly with strong networks	Improved quality of life		Medicare prevention program is feasible	

In general, the proposed hypotheses from the University of Washington, University of Pittsburgh, and Johns Hopkins University, in terms of costs to Medicare, are relatively similar. Two projects (University of Washington and University of Pittsburgh) expect a slight savings to Medicare, in terms of total health care costs, at the end of the second year of the demonstration for the experimental group. The University of Pittsburgh predicts that total Medicare costs will be higher during the first year for the group that receives the intervention. Two projects (Johns Hopkins University and University of Pittsburgh) expect inpatient costs to decrease for the experimental group in year 2. UCLA, on the other hand, does not expect any changes in the net costs of Part A and B Medicare covered services over the long run.

The hypotheses regarding utilization of health services follow a similar pattern. The University of Washington expects the experimental group to use fewer ambulatory services at the end of the second year. This group is expected to have a higher use of preventive services and a lower use of nonpreventive ambulatory services in the first year. Johns Hopkins expects that the utilization of ambulatory services among the experimental group will be higher in the first year, but similar in the second year, when compared to the control group. The use of inpatient services among the experimental group in the Johns Hopkins demonstration project is expected to be lower relative to the control group in the second year, but no different in the first year. In addition, Johns Hopkins expects to see differences in the characteristics of those who seek and receive preventive services, compared to those who do not actively seek preventive services. The University of Pittsburgh also expects a decrease in hospital utilization rates, but that the decrease will vary by condition. UCLA expects to see an increase in the use of preventive services.

Hypotheses regarding the effect of the demonstration on the functional and health status of participants vary considerably by project. The University of Washington expects a 50 percent reduction in the rate of decline in the functional status of the experimental group. Johns Hopkins University hypothesizes several effects of preventive services: rates of death and institutionalization will be lower at the end of the second year; smokers and

alcohol users will be likely to reduce or quit; appropriate nutrition, diet, and exercise will increase; indices for mental health and quality of life will be higher at the end of the second year; lower disability days, higher self evaluations and satisfaction will be evident. The University of Pittsburgh also expects lower mortality and morbidity rates among the experimental group, but expects that the demonstration will have limited effects on activities of daily living (ADLs) or independent activities of daily living (IADLs). UCLA expects that the experimental group will have a higher level of functional status after 2 years compared to the control group. In addition, the expanded coverage for preventive services is expected to reduce health risk factors (e.g., smoking, obesity, and hypertension.)

The types of outcome measures that each project plans to use to verify these hypotheses include quantifying changes in outpatient and inpatient costs and changes in utilization of inpatient services (days, admissions) and ambulatory services (visits). Some projects will be examining these costs and utilization rates by certain conditions or diagnoses. In addition, some projects will be examining utilization changes in several other services such as long term care, ancillary services, prescription services, and preventive services. The HMO-based demonstration projects may also examine in-plan versus out-of-plan use as well.

The outcomes used to identify changes in functional and health status typically include measures of quality of life, satisfaction, productivity, social supports, and cognitive measures. In addition, other measures are used to determine changes in the level of restriction or mobility of the participant such as bed and disability days and ADLs and IADLs.

2.4.4 Data Collection Instruments and Sources of Data

Demonstration projects are using a variety of data collection instruments to collect the necessary information (see Exhibit 2-6). Most

Exhibit 2-6

Data Collection Instruments and Sources of Cost/Utilization Data of Demonstrations

	UCLA	WASHINGTON	JOHN HOPKINS	PITTSBURGH	SAN DIEGO
Functional Status	Adapted Functional Status Questionnaire	Quality of Well-Being Index	Quality of Well Being Index	Health Risk Assessment	Quality of Well Being Index
Social Network	Lubben Social Network Scale/ Berkenovic Social Support	Ware Positive Affect/Depuy Vitality	Informal Support Questions	Informal Support Questions	- -
Health Orientation	Berkenovic Health Orientation Questions	Quality of Life/Self-rated Health	General Health Questionnaire/ Mini-Mental Status Exam	Self-rated Health Mental Status	Self-rated Health
Utilization	Project Utilization Data Medicare Parts A and B Claims	GHC Utilization Data	Medicare Parts A and B Claims	Project Utilization Data Medicare Parts A and B Claims	Secure Horizons Utilization Data
Costs	Medicare Parts A and B Claims	Cost Data Only Available for Pharmacy, Laboratory and Non-GHC Services GHC Cost Estimates for Other Services	Medicare Parts A and B Claims	Medicare Parts A and B Claims	Secure Horizons Cost Data

projects are employing some version of a functional status questionnaire to provide a comprehensive assessment of the functional and health status of the individual. For example, the questionnaire that will be used by UCLA is self-administered and measures the physical, psychological, and social functions of ambulatory patients. This instrument scores mobility, number of bed and disability days, quality of life, and productivity. UCLA will also use the Lubben Social Network Scale to assess the level of help an individual receives and requires with respect to health maintenance activities.

Three projects (University of Washington, Johns Hopkins, and San Diego) will use a standard instrument to compare the overall health status of individuals. The Quality of Well-Being Index includes questions on mobility, physical and social activity, and symptoms and problems the individual may be experiencing.

All projects will also be requesting participants to self-rate their health and functional status. Perceptions about their current health concerns, seriousness and susceptibility to illnesses, and general questions on satisfaction are included in these types of questionnaires.

The utilization and cost data will generally come from Medicare claims for the non-HMO based demonstration projects. Projects where preventive services are delivered in an HMO setting (University of Washington and San Diego State University) will be relying on in-house data bases on utilization, and enrollment data from their fiscal intermediary.

Overall, the five demonstration projects offer an opportunity to test the feasibility of providing preventive health services to the elderly. The environments of the demonstration projects are typical of many areas of the country and represent a range of health delivery settings.

It is the responsibility of the overall cross-cutting evaluation to adjust for differences in design and data collection features among the projects. The next chapter addresses this issue.

3.0 THE CROSS-CUTTING EVALUATION

As Chapter 2 shows, the five demonstration programs incorporated unique features in their designs, within general guidelines established in the legislation and by HCFA. This complicates the job of evaluating the feasibility of providing preventive services to Medicare beneficiaries based on all programs' experiences. In this section of the report, general issues affecting the cross-cutting evaluation are discussed. Then specific features of the proposed design are spelled out in some detail.

3.1 General Research Design Issues

By the end of this project, the cross-cutting evaluation will attempt to address two questions:

- What were the differences and similarities in experiences of the five separate demonstration projects in enrolling beneficiaries and providers, providing preventive and follow-up services, tracking utilization, and attaining stated goals and objectives?

- Is it cost effective to provide disease prevention and health promotion services for the elderly population, given the outcomes in the demonstration projects?

The timeframe for implementing this demonstration (2 years from the initial screening/assessment through the last followup) is very short. Preventive services by their nature have effects that are both immediate (detection of conditions) and long term (reduction of mortality, improvement in health status). Therefore, the emphasis of this evaluation is on comparing projects to determine feasibility, on the ability of individual projects to gear up and attract Medicare beneficiaries to the program, to deliver services in a timely fashion, and to track and assess those effects that can be detected within the timeframe of the study.

As early experiments in providing such services to the elderly have shown, there are formidable logistical challenges that must be overcome in order to organize and implement such a demonstration. If projects cannot enroll sufficient numbers of qualified participants, it is important to understand the reason. Inefficient project management might be the answer. If so, then steps can be taken in any future initiatives to screen programs more carefully. However, if reluctance of the elderly to participate is the primary factor, the benefits that the preventive services yield for this group may be small.

From the Government's perspective, then, the "front-end" criteria for a successful demonstration are as important as the "outcome" criteria normally used to evaluate a project. That is why the cross-cutting evaluation will combine intensive comparative case study analysis of how individual projects plans and implementations with a critical review of projects' own outcomes evaluations. The cross-cutting evaluation will also include an outcomes analysis, based on data submitted by each project. However, the ability to generalize from this analysis about individual outcomes or patterns across all projects will probably be limited. Although the cross-cutting evaluation contractor is working with the projects to develop consistent definitions and procedures for collecting and analyzing demonstration data, the projects will inevitably follow somewhat different paths as the demonstration unfolds. This diversity, and the initial diversity in the environment and history of the projects themselves, work against generalization regarding program outcomes.

3.1.1 Overview of the Design

Issues have to be addressed in the evaluation at different levels, using both "hard" data that quantify outcomes and permit statistical analysis and relatively "soft" data based on the perceptions of participants in the demonstrations. The research design for the cross-cutting evaluation has been shaped to accommodate methods developed by the individual projects and the Federal Government's overall requirements.

Determining whether or not preventive services can be delivered to Medicare beneficiaries in a cost effective manner requires, first of all, a controlled comparison of beneficiaries who received preventive services with

those who did not. Following HCFA's guidelines, each project has prescribed random assignment of a group of beneficiaries, into an experimental group (which will receive the preventive services) and a control group (which will not). Random assignment increases the chances of having "similar" groups by removing the element of choice, either on the part of the researcher (who may assign individuals based on incorrect information) and on the part of participants, who may, if given a choice, elect to participate based on some characteristic (like preference for a healthy lifestyle) that will complicate evaluation of the effects of the intervention. "Impacts" will be determined by comparing experimental and control group members across several outcome measures, adjusting for characteristics that might confound the analysis (such as differences in age and gender between the groups).

In addition to statistical tests on data collected by the demonstration projects and comparative analysis of the projects' own statistical analyses, the cross-cutting evaluation will produce a case study of implementation and operational issues across all five projects. The case study will be based on information collected in visits to the demonstration projects, through interviews with program administrators, demonstration service providers, service providers not directly involved in the demonstration and area seniors groups (e.g., American Association of Retired Persons, Legal Aid and Area Agencies on Aging).

These case studies will address the following topic areas:

- Internal program implementation issues: staffing and organization, budgeting, response to project demands;

- Marketing/beneficiary: outreach experience, planning, staffing, evaluation of the enrollment effort;

- Data system development: internal tracking, report generation, data base architecture, interaction with HCFA, interaction with the crosscutting evaluation effort;

- Program/provider relations: provider recruitment, communication; and

- Community perceptions/attitudes toward the program.

3.1.2 Cost Effectiveness Analysis

Project evaluations and the cross-cutting evaluation will use cost effectiveness analysis to organize tests of the major research issues. In this demonstration, computing the net additional cost of prevention services will be done by comparing Medicare expenditures on beneficiaries who receive prevention services (the experimental group) to expenditures of similar beneficiaries who do not (the control group). Differences will include the costs of the waivered prevention services that experimental group members receive, and differences in utilization of nonwaivered services by both groups after the prevention services are provided. The time period covered by the demonstration permits comparisons of costs over a 2-year period following the initial prevention intervention.

One obvious problem is encountered in separating costs directly attributed to the prevention demonstration from those that arise normally in providing health care to elderly beneficiaries. Waivered prevention services are easily defined, but nonwaivered Medicare expenditures incurred by experimental group members after the intervention are likely to be hard to classify. This evaluation will address this issue directly, by trying to show how much additional utilization after the initial intervention was associated with conditions uncovered by disease prevention screening (using indicators such as diagnosis). However, it would be impossible to separate out accurately all utilization and expenditure in this way across the 2-year study period. Therefore, the operative definition of net additional cost that will be used in most of the cost effectiveness analyses will be the difference in total Medicare expenditures between experimental and control group members.

3.1.3 Feasibility Criteria

As the introduction to this section of the report noted, the cross-cutting evaluation will be combining implementation data, to assess operational feasibility, with findings from the projects themselves and from original analysis regarding short and long term outcomes of the demonstration. The

section on feasibility that follows develops criteria for judging statistical findings. These criteria are in part quantitative. However, there will be instances in which the evaluators will have to draw on their "qualitative" knowledge of structural and procedural differences among the projects to enable them to shed light on observed outcomes.

Data will be collected from all five projects to answer questions that range from the very general to the very specific including, for example, the following:

- Did the interventions lead to improved health status?

- Did the intervention implemented by Johns Hopkins have a different effect on health status from UCLA's intervention?
- Did the "HMO-based" interventions (University of Washington and San Diego State) have an effect on health status that differed from the non-HMO projects?

- Did the interventions have different relative effects on health status, depending upon how functionally impaired participants were when they began the program?

A favorable outcome of the cross-cutting evaluation would be an unambiguous finding that the provision of prevention services is a feasible intervention for the elderly, across all projects. However, the likelihood of producing such irrefutable evidence in the cross-cutting evaluation is small. This is due to the large numbers of questions being raised and measures being devised to answer them; it is also due to the inevitable differences that will arise among the projects, simply because some are more successful in managing their programs than others.

Sorting out the findings that confirm expectations is a task made easier by the use of standards for judgment. In the case of research questions that project evaluators will test statistically, researchers will use standard tests for statistical significance and will require that "effects" of the intervention

be 10 percent or more to be considered policy-relevant; i.e., a 10 percent difference between experimental and control groups on any given outcome measure.

3.2 Research Issues

Within the general framework of cost effectiveness, all the evaluations will address certain common hypotheses. Individual projects may differ in their expectations; the wording presented here is based on the crosscutting evaluation design.

3.2.1 Medicare Expenditure

The disease prevention/health promotion (DP/HP) intervention will produce an increase in Medicare reimbursements in the short run (12 months after the intervention) and a decrease in the long run (24 months after the intervention), relative to reimbursements without the intervention. In this test, HMO-based programs are excluded, because Medicare payments to them are capitated, based on local Adjusted Average Per Capita Costs, and therefore constant regardless of change in utilization. The short run increase in nonwaivered service costs would be most likely caused by attention to conditions diagnosed during the DP/HP screening procedures. Long run decreases in reimbursements would reflect changes in beneficiary behavior, toward more "healthy" lifestyles, producing reductions in hospitalization and other costly utilization. The long run outcome is the most problematic, given the short study period. Much of the real change in medical care use associated with healthy lifestyles is likely to occur beyond the 2-year study period.

3.2.2 Medicare-Reimbursable Health Care Utilization

The DP/HP intervention will be associated with the following outcomes:

- no effect (or a slight increase) for hospital admissions in the short run, but a decrease in hospital admissions in the long run;

- no effect on hospital lengths of stay in the short run, but shorter stays in the long run;

- no effect on SNF nursing home admissions in the short run, but a reduction in nursing home admissions in the long run;

- an increase in physician utilization in the short run, and no net effect in the long run;

- no effect on home health visits in the short run, but an increase in the long run.

3.2.3 Functional Capacity

DP/HP will have no effect on the rate of functional decline in the short run, but will be associated with a deceleration in functional decline over the long run.

3.2.4 Health Status

DP/HP will have no effect on participants' health status in the short run, but will have a positive effect in the long run.

3.2.5 Health-Related Behaviors

DP/HP will have no effects on health-related behaviors in the short run, but will have the following effects in the long run:

- increase in reported exercise participation;

- increase in the number of "former" smokers; decrease in volume of cigarette smoking among smokers;

- decrease in alcohol consumption;

- increase in reported seat-belt usage;

- increase in reported use of home safety equipment;

- improvement in reported nutritional habits;

- more awareness/attention to health-related information;

There is likely to be some ambiguity about whether or not health promotion services of physicians, including recommendations regarding smoking, drinking, and exercise are really preventive or therapeutic for beneficiaries with certain conditions, such as heart disease. This issue cannot be settled to everyones' satisfaction in this evaluation. However, estimates of the volume and cost of preventive services will be made with and without "health promotion" services targeted to beneficiaries' pre-existing conditions.

3.3 Sample Size and the Precision of Estimates

Beneficiary samples in the five projects vary in size, partly because projects have different designs and questions they are interested in exploring. Each project's sample is adequate, however, to test with considerable precision, the kinds of hypotheses that have been outlined in this report. The total number of beneficiaries receiving services, aggregated across all five projects, should exceed 15,000. Therefore, any statistical analysis conducted as part of the cross-cutting evaluation, which will rely on project data, will also yield highly precise estimates.

For hypothesis tests based on participant-level data, the proposed sample sizes are large enough to detect extremely small effects at an appropriate level of statistical significance. For most of the tests anticipated in the cross-cutting evaluation, the sample of beneficiaries will be large enough to detect effects of 2 to 3 percent. Precision will be increased even further by applying more sophisticated multivariate statistical techniques.

Although sample sizes for the evaluation are clearly large enough, it is still important that beneficiaries who leave the program be followed up to the extent feasible. Attrition can have a distorting effect if it is

systematic. For example, if most of the participants who drop out of the experimental group are in better than average health, the remaining participants will be enough "different" from the control group to confound tests of intervention effects. Attrition cannot be entirely prevented, but a careful assessment of the implications of systematic attrition is important.

3.4 Measurement

Outcome measures and other indicators that will be used to adjust outcomes comparisons will be constructed from the minimum data set of the evaluation. This is a list of data elements that each project will be asked to collect, using common definitions of each element. The individual projects will then be able to produce hypothesis tests based on comparable indicators.

3.4.1 Outcome Measures

There are three broad categories of outcome measures that will be used: cost, utilization, and health/functional status (including healthy behaviors).

Cost measures

All cross-cutting hypotheses regarding cost refer to Medicare's share of cost, not total cost in an economic or accounting sense. Data supplied by the demonstration sites and claims data provided by HCFA will be used to construct the following measures:

- Total Part A/B charges and reimbursements per beneficiary year;
- Total Part A charges and reimbursements for hospital services per beneficiary year;
- Total Part A charges and reimbursements for nursing home services per beneficiary year;

- Total Part A charges and reimbursements for home health services per beneficiary year;

- Total Part B charges and reimbursements for physician and outpatient services per beneficiary year;

- Total Medicare charges and reimbursements for nonwaivered services per beneficiary year.

San Diego and Washington cannot produce comparable measures because their services will be delivered through HMOs, and Medicare pays a capitated rate for Medicare beneficiaries.

Utilization measures

Utilization data, for waivered and nonwaivered services, will be provided by the projects and will be extracted directly from Medicare claims. These measures will include:

- Number of hospital admissions per beneficiary year;

- Number of hospital days per beneficiary year;

- Number of nursing home admissions per beneficiary year;

- Number of nursing home days per beneficiary year;

- Number of home health visits per beneficiary year by skill: Registered Nurse (RN), home health aide, therapy, other.

An issue of analytic importance for the cross-cutting evaluation will be identification of nonwaivered utilization directly related to the prevention intervention. Standard statistical contrasts of nonwaivered utilization between experimental and control groups after the intervention will provide one such estimate. Controlling for differences in beneficiary characteristics will increase the precision of this estimate. However, the effectiveness of screening at the intervention will be tested directly by comparing coded

diagnoses from Medicare claims before and after the intervention, for beneficiaries determined at the intervention to have:

- heart disease;
- cancer (not including skin cancer).

One would expect to see an increase in claims with diagnoses related to conditions detected in screenings, immediately following the intervention, among experimental group members.

Health/Functional Status Measures

Individual projects have developed a variety of health and functional status measures. In conjunction with HCFA and the cross-cutting evaluation contractor, agreement will be reached on some common set of indicators, consistent with minimum data collection burden on participating Medicare beneficiaries.

The cross-cutting evaluation will utilize measures of health and functional status. Options include four measures of ADL, four measures of IADL, and three measures of activities requiring more stamina. Within each category, the numbers of "dependent" and "does not do" will be aggregated at baseline, 12 and 24 month intervals. The Quality of Well Being scale is another, more compact measure of health and functional status in use by several projects. The outcome measures that will be derived from these will be constructed as measures of change from one observation point to the next. The data will be examined to determine the most appropriate measure. Options include simple categorical variables (increase, decrease, no change) or some scoring system.

The category Other Health Status Measures can be treated in a similar manner, but will not be aggregated across individual components. Frequencies at observation points and across time will be studied to select measures that vary among patient types and across time. These measures will be used in tests of the sensitivity of health status characteristics to the prevention intervention.

A long list of health behaviors questions has been specified. These will be used to define behavioral subgroups, within experimental and control groups, such as "heavy smokers," "sedentary individuals," etc. Analysis of changes in reported behavior will concentrate on these subgroups and on the particular behaviors of relevance. For example, heavy smokers will be defined by the number of cigarettes smoked per day, after inspection of sample frequencies. Heavy alcohol users will be defined both by how often and how much they drink.

3.4.2 Other Measures

Three categories of variables will be used to help classify and adjust outcomes through multivariate analysis:

- Control variables: These identify study group, beneficiary status at the point of data collection (baseline, 12 months, 24 months) and the identity of the respondent on particular instruments.

- Sociodemographic variables: These assign the usual demographic categories (age, race, gender, ethnicity, education, marital status), living arrangements and degree of social interaction, economic situation (retirement status, type of residence, income class, non-Medicare coverage) and usual source of care.

- Intervention variables: These define the place and provider of the waivered services. Exposure to the demonstration will be measured in two ways: a length of exposure measure that will be important only if demonstrations are phased in and become operational at very different times and categorical variables that will define the content of the intervention in general terms.

In addition to beneficiary and program variables, recent data that describe market area sociodemographic, economic, and health resource

characteristics will be acquired. Some of these data will come from Abt Associates' County File, which has been generated for the HCFA Prospective Payment System evaluation studies, and some will be ordered from HCFA and other sources.

3.5 Data and Analysis

This section describes the data architecture of the cross-cutting evaluation. In addition, analytical techniques that will be used are described briefly.

The data base for this analysis will be organized in two parts:

- a report-oriented data base, including program statistics submitted by the demonstration projects documenting total numbers of enrollments, total numbers of attritors, total number of providers (added, left the program), and total waiver funds expended;

- an analysis-oriented data base, including Medicare claims, beneficiary and area-level information.

The analysis files will be organized into beneficiary files and program/area files.

The cross-cutting evaluation will undertake four types of analytical activity:

- program analysis, on a regular basis as part of the quarterly report process;

- critical review of the demonstration sites' program evaluations;

- statistical hypothesis testing, on the major research issues of the evaluation; and

- summary evaluation of the program.

Program Analysis

Quarterly reports to HCFA are called for as part of the cross-cutting evaluation activity. One of the functions of the cross-cutting evaluator will be to include, with each report, a brief evaluation of trends and feedback from the projects regarding problems encountered (many of which will be covered in the demonstration projects' own regular reports to HCFA). HCFA will be kept regularly informed, through these reports, of threats to the overall cross-cutting design introduced by slow rates of enrollment, high rates of attrition, etc.

Review of Individual Program Evaluations

In this part of the analysis, information collected through case study site visits and through interaction over the period of the study with demonstration program staff will be used to prepare a cross-cutting evaluation of the implementation and operational experience of the five demonstration projects. This will provide a context for the views of project staff regarding their experience.

Each project's quantitative hypothesis tests and the conclusions drawn from them will also be reviewed. The major purpose of this will be to alert outside observers to major differences in assumptions and approaches used, not to search for error.

Statistical Analysis

Simple statistical contrasts provide useful, easily explained information that complements multivariate techniques. Multivariate techniques will be used to derive estimates of the size and direction of program effects. Logit or probit models will be used to estimate program effects on measures that are categorical in construction. In addition to measures of health status, utilization measures, such as hospitalization, will be treated in a two step process. First, the probability that a beneficiary utilizes a service will be estimated through logit or probit. Then, the extent to which the service is utilized will be separately estimated through linear regression.

Summary Evaluation

Conclusions will be drawn based on two summary assessments:

- How successful were the individual demonstration projects at achieving their own objectives, regarding implementation, operation, etc.?

- Were the major research hypotheses rejectable, at a 5 percent level of significance, in all or most of the projects, and at a broader level across all projects? How many of the "significant" treatment effects met or exceeded the criterion for policy relevance (10 percent effect)?

It will not be possible to generalize from this program to predict what Medicare might achieve in savings (or incur in additional costs) if a prevention benefit were added. The demonstration projects were not selected randomly, and so although findings may be internally valid (based on scientifically appropriate research techniques applied to data from the five sites), they are not valid externally (capable of predicting, with suitable sampling weights, outcomes for the Medicare program as a whole). However, part of the summary evaluation will include a discussion of the options for Medicare in designing a benefit, including observations on financing methods based, in part, on experience with payment systems in other contexts and, in part, on findings from the demonstration.

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